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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,289	04/19/2004	Atsushi Suzuki	252095US0DIV	9907
22850 7590 06/20/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER UNDERDAHL, THANE E	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 06/20/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/826,289	Applicant(s) SUZUKI ET AL.	
	Examiner Thane Underdahl	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-6 and 11-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-6 and 11-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Applicant's reply received 3/16/07.

Claims 1, 3, 7-10, 14-23 and 27-29 have been cancelled. Claims 2, and 4-6 have been amended.

Response to Applicant's Arguments— 35 U.S.C § 112

The rejection of claims 3, 4, 5, 12, 13, 21, 22 and 23 under 35 U.S.C § 112 are dropped in view of applicant's amendment.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the applicant on 3/16/07, the 35 U.S.C § 102 (b) of the pending claims 2, 4 and 6 over Abraham et al. with support from Clarke et al. and Macheix et al. were considered but not found persuasive. However the same 35 U.S.C § 102 (b) rejection over claim 5 is withdrawn.

The Applicant argues that the teachings of Abraham et al. with the support of Clarke et al. and Macheix et al. disclose or suggest a food or beverage presently in Claim 6 that has been supplemented with ferulic acid and one of the specific options defined by (b-1), (b-2) or (b-3). The Examiner is confused since the options (b-1), (b-2) and (b-3) are written in the alternative. As such the prior art need only meet one of the options of claim 6. Option (b-1) in particular only requires a food or beverage comprising ferulic acid and caffeic acid. As mentioned in the previous action Abraham et al. shows quite clearly that their composition C+D in Table 1 (Abraham, page 16, Table 1) comprises caffeic acid, ferulic acid, mixed with coffee and water and was

administered to mice (Abraham, page 16, col 1, Materials and Methods). So Abraham continues to meet the limitations of claims 2 and 6.

Furthermore with the support of Clarke et al. and Macheix et al. Abraham still meets the limitations of claims 4 since both teach that coffee inherently contains neochlorogenic acid as well as cryptochlorogenic acid.

Therefore the rejection of 2, 4 and 6 remains and is repeated below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4, and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Abraham et al. with support from Clarke et al. (Coffee Volume 3: Physiology, 1988) and Macheix et al. (Fruit Phenolics, 1990).

These claims are drawn to a composition comprising at least two parts a) ferulic acid in combination with b) caffeic acid, or chlorogenic acid or a combination of the two. The composition can be incorporated into a food or herbal product such as coffee. Other acids that can be included in the composition are neochlorogenic acid, an isochlorogenic acid, 3,5-dicaffeoylquinic acid, cryptochlorogenic acid and 5-caffeoylquinic acid.

Abraham teach a composition that contains ferulic acid in combination with caffeic acid and chlorogenic acid. (page 16, Table 1, Code C). This composition was included in the herbal food product coffee (page 16, Table 1, Code C+D). Coffee

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contains isochlorogenic acid as well as neochlorogenic acid and 5-caffeoylquinic acid as supported by Clarke et al. (page 41 2nd paragraph) and Macheix et al. (page 23, 3rd paragraph).

Therefore the reference anticipates claims.

Response to Applicant's Arguments— 35 U.S.C § 103

Response to Applicants Amendment

In the response submitted by the applicant on 3/16/07 , the 35 U.S.C § 103 (a) rejection of pending claims 11-13, and 24-26 over Abraham as applied above in view of Hsu as supported by McGraw-Hill and Yokozawa et al. were considered but not found persuasive.

The Applicant argues similarly that the teachings of Abraham et al. with the support of Clarke et al. and Macheix et al. disclose or suggest a food or beverage presently in Claim 6 that has been supplemented with ferulic acid and one of the specific options defined by (b-1), (b-2) or (b-3). And since 11-13 and 24-26 depend from 6 these claims are also not taught by Abraham even in view of Hsu and Yokozawa. However since (b-1), (b-2) or (b-3) are written in the alternative, the prior art need only meet one of the options of claim 6. Option (b-1) in particular only requires a food or beverage comprising ferulic acid and caffeic acid. As mentioned in the previous action Abraham et al. shows quite clearly that their composition C+D in Table 1 (Abraham, page 16, Table 1) comprises caffeic acid, ferulic acid, mixed with coffee and water and was administered to mice (Abraham, page 16, col 1, Materials and Methods). So

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Abraham continues to meet the limitations of claim 6. Therefore the rejection stands and is repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Pending claims 11-13 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham as applied above in view of Hsu (U.S. Patent # 5,958,417) as supported by McGraw-Hill ("hypertension." McGraw-Hill Encyclopedia of Science and Technology.) and Yokozawa et al. (Phytotherapy Research, 1995).

These claims are drawn to a method of treatment for hypertension and high blood pressure and also for reducing a rise in blood pressure using the compositions in claim 6 and claim 8.

Abraham in the rejection listed above, anticipated the compositions of claim 6 and 8 by teaching a composition containing ferulic acid with chlorogenic acid and caffeic acid (page 16, Table 1, Code C). This composition can be a supplement added to coffee (page 16, Table 1, Code C+D).

What Abraham does not teach is the use of his composition in hypertension. The broadest definition of hypertension includes both high systolic and high diastolic pressure as supported by (McGraw-Hill, definition of "hypertension"). Therefore one of

ordinary skill in the art would recognize that the treatment of hypertension by this definition includes treating both the high systolic and diastolic pressures.

While Abraham does not teach his compositions for use as a treatment of hypertension, Hsu does. Hsu teach that *Crataegus* is a common herb used to treat hypertension and it contains the active ingredients of chlorogenic acid and caffeic acid (Hsu, col 2, lines 58-61). Yokozawa et al. supports Hsu by teaching that caffeic acid and its derivatives are effective at treating hypertension (page 107, Table 1).

It would have been obvious to someone skilled in the art, knowing the teachings of Hsu, to treat hypertension using the composition of Abraham. Hsu provides the motivation by plainly stating that caffeic acid and chlorogenic acid are known treatments for hypertension. The reasonable expectation of success is provided by Hsu who states that *Crataegus* with its active ingredients of chlorogenic acid and caffeic acid are used to treat hypertension.

Therefore the references listed above renders obvious pending claims 11-13 and 24-26.

Response to Applicant's Arguments Against Obvious-type double Patenting

Rejections

The obvious double patenting rejection of claims 1-26 over U.S. Patent Application # 11/209,672 is withdrawn after abandonment of conflicting application.

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In the response to the obvious double patenting rejection of claims [List Claims] over pending claims 2, 4-6, 11-13, and 24-26 were considered but not found persuasive. The Applicant argues that U.S. Patent # 6,310,100 fails to include ferulic acid with caffeic acid and/ or chlorogenic acid, which is required in the claimed invention. However given the broadest interpretation of claim 5 it would be obvious to include these compounds based on the teachings of Abraham as supported by Hsu and Yokozawa et al. as stated in the office action. Furthermore since both ferulic acid and caffeic acid are known anti-hypertensive compounds it would be obvious to combine them to form a new composition for the same purpose (M.P.E.P. § 2144.06).

Therefore the rejection remains and is repeated below.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Pending claims 2, 4-6, 11-13, and 24-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 in view of Abraham (Food and chemical toxicology, 1996) as supported by Hsu (U.S. Patent # 5,958,417) and Yokozawa et al. (Phytotherapy Research, 1995). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods. Patent No. 6,310,100 does not specifically claim chlorogenic or caffeic acid in combination with ferulic acid, but in claim 5 it does disclose a composition "consisting essentially of ferulic acid or a derivative thereof, and at least one other anti-hypertensive compound," which would encompass chlorogenic and caffeic acid as supported by Hsu (col 2, lines 58-60) and Yokozawa et al. (page 107, Table 1). Abraham discloses such compositions of isolated ferulic, chlorogenic, and caffeic acid that can be used to supplement food (Table 1, Code C and C+D). One of ordinary skill in the art would be motivated by U.S. Patent # 6,310,100 to combine chlorogenic and caffeic acids, which are known anti-hypertensive agents to a composition comprising ferulic acid with the expectation of successful treatment for hypertension with such a composition as supported by Hsu and Yokozawa et al.

The Examiner acknowledges that the obviousness-type double patenting of claims 2, 4-6, 11-13, and 24-26 over U.S. Patent Application # 9/922,694 is held in abeyance until allowable subject matter is identified.

Rejections Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims depend from a cancelled claim 8 and therefore cannot be Examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. with support from Clarke et al. and Macheix et al. as applied to claims 2, 4, 6 above, and further in view of Tia Maria (Def, Answers.com).

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Abraham et al. with support teach a composition with caffeic acid and coffee that inherently contains other acids such as neochlorogenic acid and cryptochlorogenic acid as supported by Clarke et al. and Macheix et al. referenced above. What Abraham et al. does not teach is the composition is incorporated into a food or beverage such as one beverage containing alcohol. However this is obvious in view of Tia Maria. Tia Maria is a coffee based liquor developed after world war II (Tia Maria, Answers.com). It would have been obvious to someone skilled in the art knowing the teaching of Abraham et al. who adds caffeic acid and coffee to create a coffee beverage expand their invention to an alcoholic beverage whose main component is coffee. The motivation is provided by Abraham et al. who successfully creates a coffee beverage with caffeic acid and the reasonable expectation of success is provided by Tia Maria who make liquor from coffee. Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 2-6 are not allowable.

In summary no claims, as written, are allowed for this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

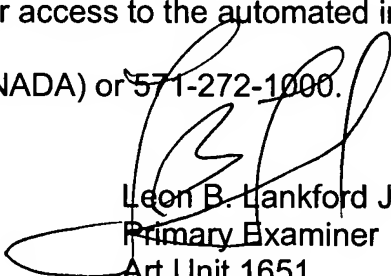
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651



Leon B. Hankford Jr
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